IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

TMT SYSTEMS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 6:20-cv-973
	)	
MEDTRONIC, INC.,	)	**JURY TRIAL REQUESTED**
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff TMT Systems, Inc. ("TMT") hereby alleges, for its Complaint against defendant Medtronic, Inc. ("Medtronic"), on personal knowledge as to TMT's own actions and on information and belief as to the actions of others, as follows:

OVERVIEW OF THE ACTION

1. This is a patent infringement action brought under 35 U.S.C. § 271 arising from Medtronic's infringement of TMT's United States Patent No. 7,101,393 (the "'393 patent") by the manufacture, use, importation, and sale of, and offer to sell, stent graft products, including the Endurant, Endurant II, and Endurant IIs stent grafts (collectively, the "Accused Products"). The Accused Products are used in the treatment of abdominal aortic aneurisms ("AAA") and incorporate TMT's patented M-stent technology as a means to seal and fixate the Accused Products to the interior walls of a patient's abdominal aorta, allowing blood flow to bypass the patient's life-threatening aneurysm. Medtronic has been infringing the '393 patent since at least late 2010 (when Medtronic received regulatory approval to market the Endurant stent graft) and has been on notice of the '393 patent since at least 2008 (when Medtronic received notice that its Endurant stent graft would infringe the '393 patent). For years, TMT attempted to settle this

dispute without judicial intervention, but Medtronic's infringing activities only grew in scope such that the Accused Products now generate billions of dollars in yearly revenue. TMT brings this action to remedy Medtronic's long-standing, ongoing and willful infringement.

THE PARTIES

2. TMT is a corporation organized and existing under the laws of Delaware, having a principal place of business at 23240 Chagrin Boulevard, Suite 600, Beachwood, Ohio 44122. TMT was founded in 2003 by Dr. Timur Sarac, who currently acts as its Chief Executive Officer. Outside of his work for TMT, Dr. Sarac is the Chief of Vascular Surgery and Director of the Aortic Center at The Ohio State University's Wexner Medical Center. Previously, Dr. Sarac was the Chief of Vascular Surgery at the Yale University Hospital and Vice Chairman of Vascular Surgery at the Cleveland Clinic. In July 2002, Dr. Sarac filed a U.S. provisional patent application disclosing a novel stent, referred to as an "M-stent," for use in the treatment of abdominal aortic aneurysms. Dr. Sarac is the sole inventor of the '393 patent, which claims priority to that 2002 provisional application.

3. Medtronic is a corporation organized and existing under the laws of the state of Minnesota, having a principal place of business at 710 Medtronic Parkway, LC300, Minneapolis, Minnesota 55432-5604, and may be served through its registered agent, Corporation Service Company, at 2345 Rice Street, Suite 230, Roseville, Minnesota 55113-5603, or wherever else it may be found. Medtronic has been registered to do business in Texas since at least 1976, has been assigned Texas Taxpayer No. 14107931835, and has a Texas registered agent, Corporation Service Company d/b/a CSC-Lawyers Inc., at 211 East 7th Street, Suite 620, Austin, Texas 78701.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Medtronic. Medtronic has continuous and systematic business contacts with the State of Texas, including with the Western District of Texas. Medtronic, directly or through subsidiaries or intermediaries (including distributors, customer service representatives, and others), conducts its business extensively throughout Texas, by shipping, distributing, offering for sale, selling, and advertising (including through interactive web pages) the Accused Products in the State of Texas and the Western District of Texas.

6. Medtronic, directly and through subsidiaries or intermediaries (including distributors, customer service representatives, and others), has purposefully and voluntarily placed its infringing Accused Products into this District and into the stream of commerce with the intention and expectation that the Accused Products will be purchased and used in this District. Medtronic has offered and sold and continues to offer and sell the Accused Products for delivery and use in this District.

7. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Medtronic committed acts of infringement in this judicial district and has a regular and established place of business in this judicial district.

8. Medtronic conducts business, itself and through its agents, from at least one permanent, physical location in this District, located at 18302 Talavera Ridge, San Antonio, Texas 78257 (the "San Antonio Facility"). Medtronic has continuously conducted business from the San Antonio Facility since at least 2009, including through the direct employment of people physically located at this facility. These Medtronic employees perform vital business functions for

Medtronic, including customer service, human resources, facility management, and information technology support and management. As of November 1, 2017, Medtronic had at least 21 employees working at the San Antonio Facility who are paid separately from employees of any Medtronic affiliate working at the same location.

9. Medtronic lists "San Antonio, TX" on the Medtronic.com website as one of the "Medtronic Locations" and, more specifically, as one of its "Regional Locations" within the United States. Medtronic does not specify any other entity (i.e., a subsidiary or other affiliated entity) as resident in this or any other listed "United States" location. In contrast, Medtronic lists distinct affiliated entities—not Medtronic, Inc.—as resident in each of the Regional Locations *outside* the United States. The Medtronic.com website is registered to Medtronic.

10. The San Antonio Facility bears the official, trademarked Medtronic logo, as shown below from a March 2020 Google Maps image capture:

11. Medtronic is the record owner of the Medtronic trademark registrations in the United States. For example, Medtronic owns U.S. Trademark Registration No. 2,884,251 relating to the stylized Medtronic logo shown in the image above. Medtronic authorized the placement of its trademarked logo on the San Antonio Facility to prominently convey to the public that this facility is a regular and established place of business for Medtronic.

12. Medtronic either leases or subleases the San Antonio Facility, or portions thereof, from its wholly-owned subsidiary MiniMed, Inc., or receives access to and use of the San Antonio Facility by Medtronic's employees in this District on a regular and established basis for no consideration by virtue of Medtronic's control of MiniMed, Inc. as its wholly-owned subsidiary. Medtronic's employees in this District conduct Medtronic's business at the San Antonio Facility on a regular and established basis. These employees have workstations and offices at the San Antonio Facility, use Medtronic computers at their workstations and offices in the San Antonio Facility, access Medtronic's intranet to perform their duties at the San Antonio Facility, have dedicated telephones and telephone numbers to make and receive telephone calls at the San Antonio Facility, and receive mail and courier deliveries on behalf of Medtronic at the San Antonio Facility. In addition, as Medtronic employees, they are permitted to park their automobiles at the San Antonio Facility.

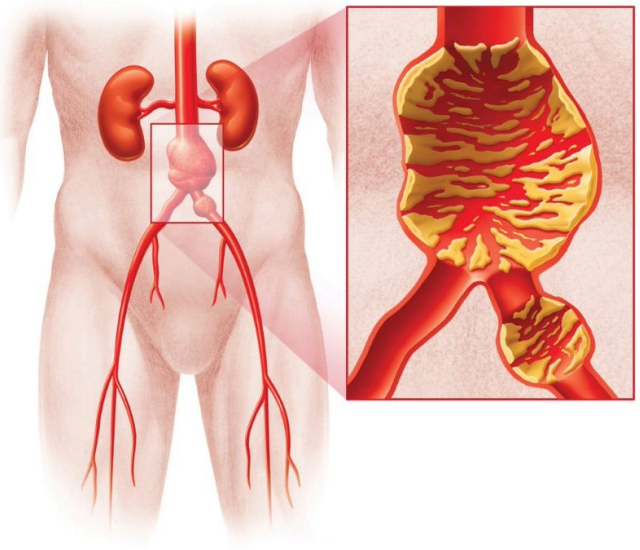
13. Medtronic also conducts business directly from home offices of multiple employees who permanently reside in this District and work from their home offices, whereby each such home office is a permanent, physical location in this District. Such Medtronic employees perform vital business functions, including executive-level management, corporate training, and clinical research management, and use their home offices as Medtronic's regular and established places of

business in this District. As of November 1, 2017, Medtronic had at least three employees permanently and regularly working from home offices in this District.

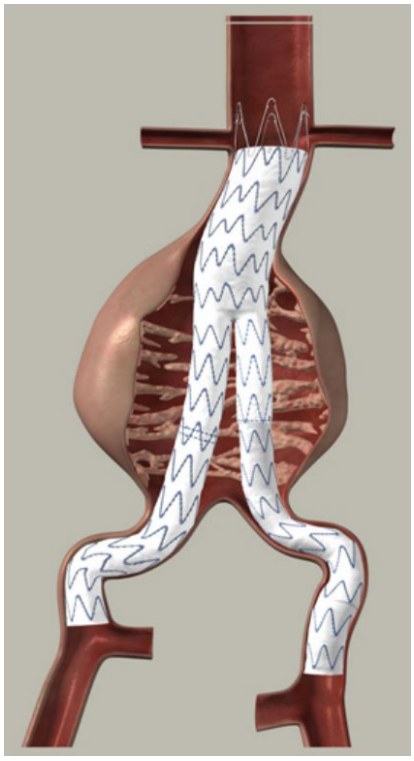
14. Medtronic has committed acts of infringement in this District by offering for sale and selling the Accused Products for delivery and use in this District. Pursuant to these sales, Medtronic has delivered (either itself or through authorized agents) the Accused Products at multiple healthcare facilities in this District. Medtronic has also induced infringement in this District by providing manuals and documentation teaching use of the infringing Accused Products by physicians who work and reside in this District.

BACKGROUND OF THE INVENTION

15. An AAA (abdominal aortic aneurysm) is an abnormal enlargement of the arterial walls of the aorta at the level of the abdomen, usually below the renal arteries, and may extend into the common iliac arteries. This enlargement can rupture, which results in life-threatening internal bleeding. An AAA is depicted in the illustration below:



16. An AAA is typically treated using a minimally invasive procedure called endovascular stent grafting. A stent graft comprises flexible wire frames (i.e., the "stents") integrated with a woven fabric tube (i.e., the "graft"). As depicted below, the anatomy of the abdominal aorta requires an AAA stent graft to roughly form the shape of an upside down "Y," enabling the graft to split blood flow from the renal artery across the two subsequent iliac arteries. During the procedure, the stent graft is originally in a compressed state and placed inside the aortic aneurysm with the help of a plastic tube (referred to as a delivery sheath). As depicted in the illustration below, once in place, the stent graft is expanded (either through self-expanding means or via balloon expansion) to the edges of the healthy parts of the blood vessels and creates a new path for blood to flow.



17. Proper placement of a stent graft reduces pressure on the aneurysm and essentially eliminates the risk of rupture, subsequent internal bleeding and death. A typical AAA stent graft has three primary anchoring points, one in each of the vessels that frame the aneurysm. Prior art

stents, however, had issues with anchoring that allowed leaks around the stent that can lead to expansion of the aneurysm and possible rupture. In addition, an AAA can come in different sizes and shapes and there may be multiple aneurysms throughout the anatomy of the abdominal aorta. Early versions of AAA stent grafts had limited ability to conform to the specific needs of patients and, instead, were designed to address standard aneurysms in a typical anatomy (i.e., cylindrical vessel walls).

18. Dr. Sarac solved this problem with his M-stent. The M-stent allows multiple planes of movement for the stents within the AAA stent graft, resulting in more consistent anchoring and creating a better anatomical fit when treating a non-standard AAA or when the anatomy of the patient skewed from normal. Studies conducted on the Accused Products show reduced instances of leakage and graft failures compared to AAA stent grafts that do not incorporate the M-stent.

19. Dr. Sarac has received patent protection on his M-stent. On September 5, 2006, the United States Patent and Trademark Office ("USPTO") duly issued the '393 patent, entitled "Percutaneous Endovascular Apparatus for Repair of Aneurysms and Arterial Blockages." A true and correct copy of the '393 patent is attached hereto as Exhibit 1. The '393 patent claims priority to U.S. Provisional Patent Application No. 60/397,745, filed on July 22, 2002.

20. The '393 patent has been in full force and effect since its issuance. TMT owns by assignment the entire right, title, and interest in and to the '393 patent, including the right to seek damages for past, current, and future infringement thereof.

MEDTRONIC'S DEVELOPMENT OF THE ENDURANT M-STENT

21. From April to June 2003, Dr. Sarac met with Trevor Greenan, an engineer having substantial experience with stent grafts, to discuss fabricating advanced prototypes of Dr. Sarac's

novel M-stent. In August 2003, TMT and Greenan entered into a Mutual Confidentiality Agreement, a true and correct copy of which is attached hereto as Exhibit 2.

22. After signing the Mutual Confidentiality Agreement, Dr. Sarac allowed Greenan to examine confidential drawings and designs of Dr. Sarac's M-stent. Not long thereafter, Greenan abruptly ceased communicating with Dr. Sarac and did no work for TMT. In 2004, and unknown to Dr. Sarac at the time, Medtronic hired Greenan for an engineering position to work on an improved stent graft to treat AAA.

23. Without Dr. Sarac's knowledge or consent, Greenan used Dr. Sarac's novel M-stent to develop Medtronic's Endurant product. Two years later, in November 2006, Medtronic filed a U.S. patent application (No. 11/559,723), disclosing an "M shape" stent and listing Greenan as one of the inventors. The application eventually issued as U.S. Patent No. 7,615,072 (the "'072 patent") in 2009. At no time during prosecution of the '072 patent did Medtronic disclose Dr. Sarac's novel M-stent to the USPTO, even though the application for the '393 patent was published in June 2004, Greenan was aware of the application since at least the fall of 2005, and Medtronic was put on notice of the patent at least as of July 2008, as detailed below.

24. In 2008, Medtronic introduced the Endurant stent graft in Europe. The Food and Drug Administration approved the Endurant stent graft in 2010, the Endurant II stent graft in 2012, and the Endurant IIs stent graft in 2014. Medtronic touts the "M-shaped proximal stents" of the Endurant stent grafts as providing "[o]ptimal seal and fixation." The Endurant stent grafts have been wildly successful, eventually capturing over fifty percent of the market for stent grafts used to treat AAA in the United States. Medtronic is well aware that Endurant's use of "M-shaped proximal stents"—as claimed in the '393 patent—has been the driving force behind the medical community's widespread adoption of Endurant as the most effective treatment for AAA.

25. After learning of Medtronic's Endurant stent graft in 2008, Dr. Sarac repeatedly sought to communicate with Medtronic regarding its infringement of the '393 patent. For example, in a July 11, 2008 email to James Machek, then Senior Director of Research and Development at Medtronic, Dr. Sarac stated: "In following up regarding the patents we discussed, I have 1 utility issued which involves an M-stent and also telescoping expandable stent. There are also 3 CIPs filed. This concept has been discussed in the past with 2 of your engineers before they worked for Medtronic." Dr. Sarac's only patent as of July 1, 2008 was the '393 patent. Medtronic's response was to stonewall, denying infringement (but without any specifics) or any knowledge of Dr. Sarac's prior discussions with Medtronic engineers such as Mr. Greenan.

26. Dr. Sarac persisted in his efforts to communicate with Medtronic over the course of many years, refusing to accept that Medtronic would so blatantly incorporate his novel M-stent into its products without just compensation. At times, Medtronic appeared willing to engage with Dr. Sarac, taking advantage of Dr. Sarac's belief that Medtronic, eventually, would own up to its misconduct. In reality, Medtronic never intended to provide any compensation to Dr. Sarac for its knowing usurpation of his invention, using intermittent, and occasionally encouraging, communications to keep him at bay.

COUNT I

(Infringement of U.S. Patent No. 7,101,393)

27. TMT incorporates herein by reference paragraphs 1 through 26 above as if set forth in full.

28. Medtronic has infringed and continues to infringe the '393 patent, including at least claim 23, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making,

offering to sell, and/or selling within the United States, and/or importing into and/or exporting from the United States, without authority or license, the Accused Products.

29. Medtronic has infringed and continues to infringe the '393 patent, including at least claim 23, pursuant to 35 U.S.C. § 271(b), by (among other things) actively aiding and abetting infringement by others, including customers such as health care providers and physicians. As set forth in paragraph 25, Medtronic was aware of the '393 patent at least as of July 11, 2008, when Dr. Sarac emailed Mr. Machek about TMT's patented M-stent technology. Notwithstanding its knowledge of the '393 patent, and its knowing incorporation of TMT's M-stent technology into the Accused Products, Medtronic has offered to sell and sold, and continues to offer to sell and sell, the Accused Products with the knowledge and specific intent to encourage and facilitate infringing uses of such products by its customers both inside and outside the United States. Medtronic has induced, and continues to induce, this direct infringement through its affirmative acts of manufacturing, selling, and distributing the Accused Products, and providing documentation and other information to customers such as health care providers and physicians instructing them to use the Accused Products in an infringing manner.

30. Medtronic has infringed, and continues to infringe, the '393 patent, including at least claim 23, pursuant to 35 U.S.C. § 271(c), by contributing to direct infringement committed by customers such as health care providers and physicians in this District and elsewhere in the United States. Medtronic's affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Products and causing the Accused Products to be manufactured, used, sold, and offered for sale, contribute to its customers' use of the Accused Products, such that the '393 patent is directly infringed. The Accused Products are a material part of the invention of the '393 patent, are not staple articles or commodities of commerce, have no

substantial non-infringing use, and are known by Medtronic to be especially made or adapted for use in the infringement of the '393 patent. Medtronic has known of the '393 patent and its incorporation of TMT's patented M-stent technology into the Accused Products since at least July 11, 2008. Despite this knowledge of the '393 patent and that the Accused Products infringe the '393 patent, Medtronic has performed and continues to perform these affirmative with the specific intent that they cause the direct infringement of the '393 patent.

31. Claim 23 of the '393 patent is reproduced below with the addition of labels [a], [b], and [c] corresponding to limitations of the claim:

> 23. An endovascular apparatus comprising:
>
> [a] a tubular sleeve having a cranial end, a first caudal branch, and a second caudal branch; and
>
> [b] first, second, and third expandable attachment devices attached to the cranial end, the first caudal branch, and the second caudal branch of the tubular sleeve, respectively, to hold the sleeve open and secure the sleeve to a wall of a lumen, the first, second, and third attachment devices being expandable from a first state to a second state and each comprising:
>
> [c] a plurality of telescoping arms, the arms being operatively connected to one another so as to form a perimeter of variable length, and the arms further being operatively coupled to one another at an angle so that four telescoping arms form the shape of an M configuration when viewed from within a plane defined by the perimeter of variable length.

32. The Accused Products embody each and every limitation of at least claim 23 of the '393 patent, literally or under the doctrine of equivalents, as described in the non-limiting examples

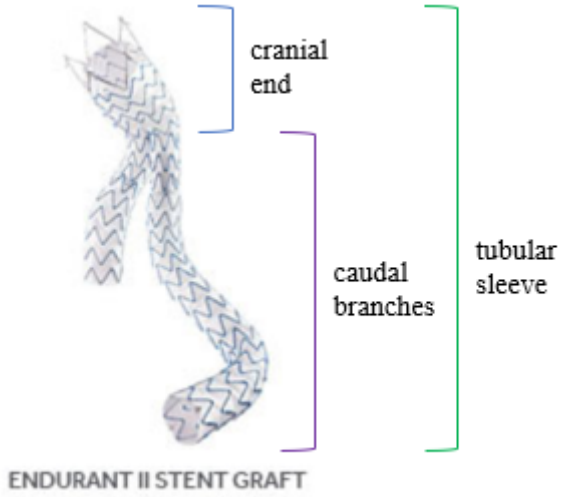
set forth below from the Endurant II stent graft. The Endurant I and Endurant IIs stent grafts have the same features described below and embody each and every limitation of at least claim 23 of the '393 patent for the same reasons as does the Endurant II stent graft. These non-limiting examples are preliminary and are not intended to limit Medtronic's right to modify these non-limiting examples or allege that other aspects of the Accused Products infringe claim 23 or any other claims of the '393 patent.

"23. An endovascular apparatus comprising:"

33. Medtronic's website explains that "[t]he Endurant II/Endurant IIs bifurcated stent grafts are indicated for the ***endovascular treatment*** of infrarenal abdominal aortic or aortoiliac aneurysms." The Endurant II stent graft is thus an endovascular apparatus.

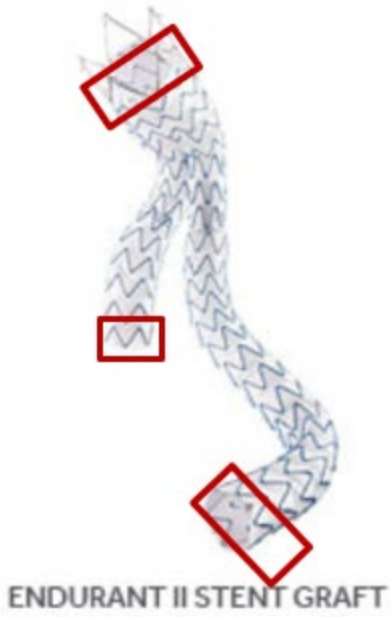
"[a] a tubular sleeve having a cranial end, a first caudal branch, and a second caudal branch; and"

34. The Endurant II stent graft includes a tubular sleeve having a cranial end, a first caudal branch, and a second caudal branch. As depicted in the annotated figure below, which is an image of the Endurant II stent graft, the tubular sleeve (green), which spans the length of the Endurant II stent graft, includes a cranial end (blue), corresponding to the upper portion of the tubular sleeve, and first and second caudal branches (purple), corresponding to the lower portion of the tubular sleeve.

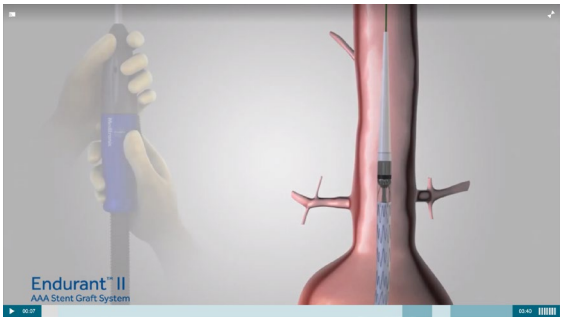


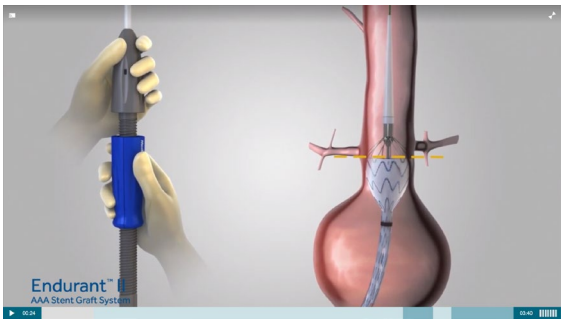
"[b] first, second, and third expandable attachment devices attached to the cranial end, the first caudal branch, and the second caudal branch of the tubular sleeve, respectively, to hold the sleeve open and secure the sleeve to a wall of a lumen, the first, second, and third attachment devices being expandable from a first state to a second state and each comprising:"

35. The Endurant II stent graft includes first, second, and third expandable attachment devices attached to the cranial end, the first caudal branch, and the second caudal branch of the tubular sleeve, respectively, to hold the sleeve open and secure the sleeve to a wall of a lumen. As depicted in the annotated figure below, which is an image of the Endurant II stent graft, the expandable attachment devices are attached to the cranial end, the first caudal branch, and the second caudal branch of the tubular sleeve.

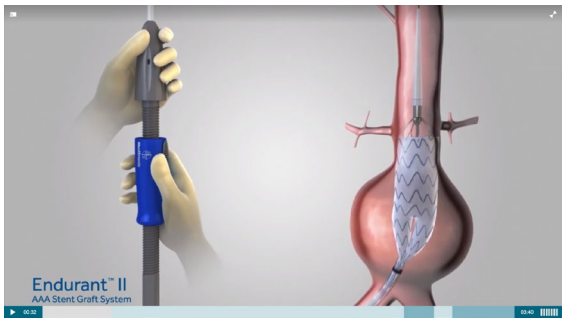


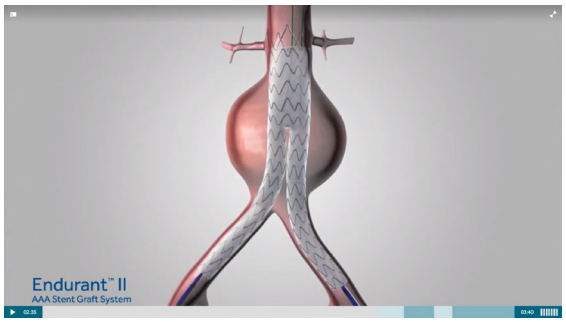
36. In addition, the first, second, and third attachment devices of the Endurant II stent graft is expandable from a first state to a second state. Medtronic's animation of the deployment of the Endurant II stent graft, available at https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/aortic-stent-grafts/endurantii.html, depicts the first, second, and third attachment devices being expandable from a first state to a second state. The figures below depict images captured from that animation of the first attachment device attached to the cranial end and expandable from a first state (left figure) to a second state (right figure).





37. The figures below depict images captures from that animation of the second and third attachment devices attached to the first and second caudal branches and expandable from a first state (left figure) to a second state (right figure).

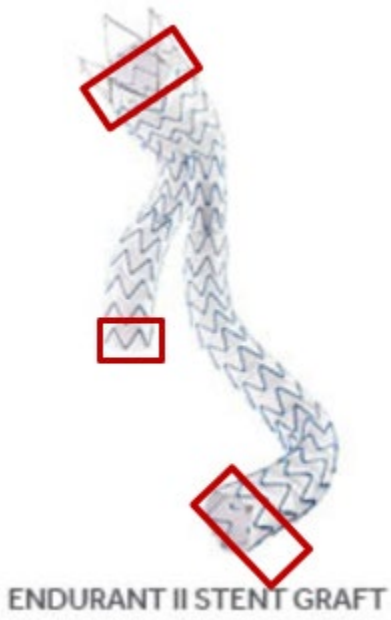




"[c] a plurality of telescoping arms, the arms being operatively connected to one another so as to form a perimeter of variable length, and the arms further being operatively coupled to one another at an angle so that four telescoping arms form the shape of an M configuration when viewed from within a plane defined by the perimeter of variable length."

38. Medtronic's website explains that to achieve "[o]ptimal sealing and fixation," "M-shaped proximal stents provide wall apposition and minimize in-folding. Suprarenal stent anchor pins provide secure fixation." As shown in the annotated figures following paragraph 39, which are images of the Endurant II stent graft, the M-shaped proximal stents include four arms in the shape of an M capable of expansion and contraction in the manner of an accordion and are thus telescoping arms operatively connected to one another so as to form a perimeter of variable length. In addition, the images following paragraphs 36 and 37 show that the perimeters at the cranial end, the first caudal branch, and the second caudal branch are expandable and are thus perimeters of variable length.

39. As depicted in the annotated figures below, which are images of the Endurant II stent graft, the telescoping arms are operatively coupled to one another at an angle so that four telescoping arms form the shape of an M configuration. The shape of an M configuration is highlighted in red and is viewed from within a plane defined by the perimeter of variable length.



40. As a result of Medtronic's infringement of the '393 patent, TMT has been damaged. TMT is entitled to recover for damages sustained as a result of Medtronic's acts of infringement in an amount subject to proof at trial.

41. Medtronic's infringement of the '393 patent has been and continues to be willful. For example, as set forth in paragraphs 24 through 26, Medtronic was aware of the '393 patent at least as of July 11, 2008, when Dr. Sarac emailed Mr. Machek about TMT's patented M-stent technology. Medtronic has deliberately continued to infringe in a wanton, malicious, and

egregious manner, with reckless disregard for TMT's patent rights. Thus, Medtronic's infringing actions have been and continue to be consciously wrongful.

42. Medtronic's inexcusable usurpation of TMT's invention, and willful infringement of the '393 patent, make this an exceptional case that warrants an award of attorneys' fees to TMT pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, TMT prays for a judgment in its favor and against Medtronic and respectfully requests the following relief:

A. A judgment that Medtronic directly infringes, induces infringement of, and contributorily infringes the '393 patent;

B. A judgment that Medtronic willfully infringes the '393 patent;

C. Damages for infringement of the '393 patent in an amount to be determined at trial;

D. Trebling of all damages awarded on account of Medtronic's willful infringement of the '393 patent;

E. For other monetary relief, including costs and expenses and pre- and post-judgment interest;

F. A determination that this is an exceptional case under 35 U.S.C. § 285 and an award of attorneys' fees and costs to TMT; and

G. An order awarding TMT any such other relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, TMT hereby demands a jury trial as to all issues so triable.

DATED: OCTOBER 16, 2020

CAPSHAW DERIEUX, LLP

/s/ *Elizabeth L. DeRieux*

Elizabeth L. DeRieux
Texas State Bar No. 05770585
114 East Commerce Avenue
Gladewater, Texas 75647
(903) 845-5770
ederieux@capshawlaw.com

Attorneys for Plaintiff
TMT Systems, Inc.

OF COUNSEL:
David I. Gindler
Lauren Drake
MILBANK LLP
2029 Century Park East, 33rd Floor
Los Angeles, CA 90067-3019
(424) 386-4000

Javier Ramos
MILBANK LLP
1850 K Street, NW
Washington, DC 20006
(202) 835-7500

Jordan Fernandes
MILBANK LLP
55 Hudson Yards
New York, NY 10001-2163
(212) 530-5000